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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,867	09/16/2005	Tanya Kathleen Church	270851US0PCT	5987

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EXAMINER	
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ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
08/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/531,867	CHURCH ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2009*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 12-22* is/are pending in the application.

4a) Of the above claim(s) *18-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12-17* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9 and 12-22 are pending. Claims 18-22 are withdrawn from consideration by original presentation as being drawn to a non-elected invention. Claims 1-9 and 12-21 have been amended. Claim 22 is new. Claims 10-11 are cancelled. Claims 1-9 and 12-17 are under consideration in the instant office action. Receipt and consideration of Applicants' amended claim set and remarks/arguments submitted on April 30, 2009 are acknowledged. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments.

Election/Restrictions

Newly submitted amended claims 18-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: no previously examined claim was drawn to a method of treatment (i.e. a method of using) the examined composition claims. The claimed composition can be used in a materially different method, such as in a method to suppress premature labor (i.e. relaxation of uterine muscle tissue).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, **claims 18-22 are withdrawn from consideration as being directed to a non-elected invention.** See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is internally inconsistent, because it is drawn to a method of preparing a pharmaceutical formulation according to claim 1, which is a formulation requiring the addition of a mineral acid to obtain a pH from2.5-5.5; however, claim 16 indicates that adjusting the pH of the solution (i.e. adding acid) is optional. The formulation of claim 1 cannot be made unless acid is added to adjust the pH. Thus, indication of step (b) of claim 16 as being optional does not make the formulation of parent claim 1, rendering claim 16 internally inconsistent.

The remaining claims are rejected as depending from a rejected claim.

Claim Objections

Claim 17 is objected to because of the following informalities: the word "in" located on line 2 of claim 17 should be "is". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 12-13, and 15 are rejected under 35 U.S.C. 103 (a) as being unpatentable over McNamara et al. (U.S. Patent No. 6,423,298).

Applicant Claims

Applicants claim a pharmaceutical aerosol formulation comprising (i) dissolved salmeterol, (ii) a liquefied HFA propellant system, (iii) co-solvent in an amount of no more than 35% w/w, and (iv) water in an amount of 0-5% w/w.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

McNamara teaches **pharmaceutical aerosol formulations** comprising two or more active substances and **HFC propellant**, wherein at least one active substance **is dissolved** and at

least one other active substance is in the form of suspended particles (title; abstract; and col. 2, lines 17-29). The HFC propellant comprises TG 134a (i.e. HFA 134a), TG 227 (i.e. HFA 227), or mixtures thereof (col. 2, lines 21-24). Suitable active agents include **beclomethasone, budesonide, fluticasone, ipratropium bromide, oxitropium bromide, salmeterol, and the esters, salts, and/or solvates thereof** (col. 2, lines 30-46). Which active is in solution and which active is in suspension can be determined quickly by solution and suspension trials (col. 2, lines 41-46).

Suitable cosolvents are pharmacologically acceptable alcohols (e.g. ethanol), esters, water, or mixtures thereof, wherein **ethanol is preferred** (col. 3, lines 50-55). **Suitable amounts of cosolvent range from 0.0001-50% w/w, preferably 0.001-25% w/w or in an alternative embodiment from 0.001-10% w/w** (col. 3, lines 52-55). In preferred embodiments just enough alcohol is added to dissolve the active that is required to be in solution (Id.).

In one embodiment stabilizers are added to the formulation, wherein **preferred stabilizers are those which influence pH, such as hydrochloric acid, sulfuric acid, nitric acid, phosphoric acid, ascorbic acid, and citric acid** (col. 3, line 64 through col. 4, line 11). **Stabilizers are used in amounts up to 1,000 ppm, most preferably 20-40 ppm** (col. 4, lines 13-15; claims 8-13). By illustration, assuming a total formulation mass of 100 grams and that the resulting formulation has a density of about 1 g/mL (i.e. a volume of 100 mL), 1,000 ppm (i.e. 0.1 g of acid), 100 ppm (i.e. 0.01 g of acid), 10 ppm (i.e. 0.001 g of acid), and 1 ppm (i.e. 0.0001 g of acid) of HCl acid added to stabilize the formulation would reasonably correlate to pH values of 1.56, 2.56, 3.56, and 4.56, respectively. McNamara exemplifies compositions comprising two or more medicaments (e.g. ipratropium bromide [dissolved] with albuterol

sulfate [suspended] or chromoglycate [suspended] with fenoterol hydrobromide [dissolved]), **wherein the amount of the medicaments ranges from 0.004% w/w to 0.21% w/w**) (Examples 1-4: col. 4, lines 20-44).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

McNamara does not exemplify formulations wherein salmeterol is dissolved in solution; however, McNamara's teachings do suggest such formulations.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious at the time of the instant invention to follow the teachings of McNamara and obtain a solution formulation of salmeterol, which also comprises a second different suspended active agent, because McNamara indicates that salmeterol is a suitable active agent for incorporation in the invented formulations. Although McNamara does not exemplify a formulation comprising salmeterol or explicitly state that salmeterol is in solution, it is noted that the amounts of cosolvent indicated as being suitable overlap with those recited in Applicants' claims. As a result it is a reasonable conclusion that salmeterol present in McNamara's formulations would necessarily be dissolved (i.e. in solution). An ordinary skilled artisan would have been motivated to select salmeterol as one of the active agents, because it is explicitly identified by McNamara as being a suitable medicament (e.g. McNamara's claim 20). An ordinary skilled artisan would have had a reasonable expectation of obtaining a solution of salmeterol, because the cosolvent amounts taught by McNamara overlap with the amounts

recited in Applicants' claims and it is well known that the addition of more solvent is one means to solubilize a solvent.

Regarding the specific amounts of active agent salmeterol, water, and ethanol, McNamara teaches overlapping amounts. A prima facie case of obviousness necessarily exists when the prior art range overlaps or touches a claimed range, such as in the instant rejection. MPEP § 2144.05. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Regarding the recited pH values, McNamara teaches overlapping amounts of acid stabilizer and explicitly identifies mineral acids (e.g. HCl and sulfuric acid) as suitable acids to stabilize the active agents. See the calculated estimated pH's above. Furthermore, regarding the properties recited in claims 6-7 of the instant application, because McNamara is highly suggestive of the claimed compositions, McNamara's suggested compositions would reasonably be expected to exhibit the same or substantially similar properties. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 8-9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNamara et al. (U.S. Patent No. 6,423,298) as applied to claims 1-7, 12-13, and 15 above, and further in view of Keller et al. (WO 00/06121), wherein U.S. Patent No. 6,585,958 is being used as the English language equivalent.

Applicant Claims

Applicants claim a pharmaceutical aerosol formulation as described above, wherein the formulation comprises salmeterol xinafoate (claim 8) in an amount of 0.005 to 0.15 % w/v (claim 9) and the formulations are filled into a container made of a material, such as standard aluminum.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of McNamara are set forth above.

Keller establishes that **salmeterol xinafoate is a known salt of salmeterol** that is suitable for pharmaceutical inhalation aerosol formulations (Example 10: col. 13, lines 32-44). Keller also establishes that **fluticasone propionate** (Example 9: col. 13, lines 20-31) and **beclomethasone dipropionate** (Example 5: col. 12, lines 42-54) are known esters of these corticosteroids. Suitable amounts of medicaments for inclusion in Keller's invented suspensions and solutions are generally amounts of at least 0.0001 to approximately 5% w/w.

Keller teaches that the formulations can be filled into containers using known methods, such as cold-filling or pressure-filling techniques, wherein **suitable containers are pressure-resistant containers made of plastic, glass, or *aluminum*** that can be equipped with metered-

dose valves (e.g. 10 to 140 microliter metered-dose valves) (col. 11, lines 12-19). Keller also teaches that the filling of propellant into the pressure-resistant container occurs after sealing and evacuating, which reads on gassing (Example 10).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

McNamara lacks the teachings of compositions comprising salmeterol xinafoate or compositions filled into a standard aluminum. These deficiencies are cured by Keller.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious at the time of the instant invention to modify the compositions of McNamara to utilize salmeterol xinafoate, because McNamara teaches that the suitable active agents may be used in the form of their esters, salts, or solvates thereof and salmeterol xinafoate is a well known salt of salmeterol (Keller). An ordinary skilled artisan would have been motivated to utilize salmeterol xinafoate and would have had a reasonable expectation of obtaining a solution HFA formulation, because McNamara teaches that the suitable active agents may be used in the form of their esters, salts, or solvates thereof and salmeterol xinafoate is a well known salt of salmeterol (Keller).

Regarding the filling of the compositions into a standard aluminum container, it would have been prima facie obvious to fill the invented formulations into a pressure-resistant container made from conventional materials, such as standard aluminum. Although Keller does not explicitly state that the aluminum containers that are indicated as being suitable are made from

"standard aluminum" it would have been prima facie obvious for the ordinary skilled artisan to utilize a conventional (i.e. standard material). An ordinary skilled artisan would have been motivated to fill the compositions into a standard aluminum pressure-resistant container and would have had a reasonable expectation of doing so, because Keller teaches that suitable pressure-resistant containers may be made from aluminum and by definition standard aluminum is conventional. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 8-9 and 14 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNamara et al. (U.S. Patent No. 6,423,298) as applied to claims 1-7, 12-13, and 15 above, and further in view of Wulffhart et al. (U.S. Patent No. 6,455,028).

Applicant Claims

Applicants claim a method of making the formulation of claim 1, as described in claim 16, wherein in some embodiments the actuator orifice has a diameter of 0.22 mm.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of McNamara are set forth above.

Wulffhart describes conventional filling techniques used to fill metered dose inhalers comprising a pressure-resistant container (e.g. an aluminum canister) with pharmaceutical aerosol formulations, which entails filling the canister with liquefied propellant and additional

formulations components, and finished by crimping an actuating valve onto a canister (col. 10, lines 14 through col. 15, line 26, especially col. 10, lines 55-64, 23-26, and 42-43). Wulffhart identifies actuators with a 0.33 mm orifice as being commercially available (col. 13, lines 21-23).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

McNamara lacks the teaching of a process of making a pharmaceutical formulation comprising the step of crimping a valve onto a container. This deficiency is cured by Wulffhart.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious at the time of the instant invention to obtain a MDI using the process of Applicants' claim 16 for the following reasons. It is logical that one must make a solution before it can be in a container, such as by mixing all the required components (steps (a)-(b) and (e)). McNamara suggests the claimed solution formulations and teaches that these are to be filled into a pressure resistant container fitted with a metering valve. McNamara does not explicitly state that the metering valve is attached by crimping, however, as evidenced by the teachings of Wulffhart crimping is the conventional method to attach a valve to a pressure resistant container. It is noted that McNamara's example 10 establishes that "gassing" (i.e. sealing and evacuating) is a conventional step in preparing MDI's containing aerosol pharmaceutical formulations. Although the cited references do not teach the recited method steps in the same order, the variation of the order of steps is prima facie obvious, absent the showing of the criticality of a particular order of steps. Regarding the actuator orifice, Wulffhart

teaches that 0.33 mm actuator orifices are commercially available. It is the Examiner's position that a 0.33 mm actuator orifice would reasonably be expected to exhibit the same or substantially similar properties as a 0.22 mm actuator orifice. Furthermore, the selection of an actuator orifice diameter is merely a design choice well within the capability of the ordinary skilled artisan, which only requires the selection of an actuator orifice diameter from those that are commercially available (See Cripps WO 01/47493; of record). For the aforementioned reasons an ordinary skilled artisan would have been motivated to utilize conventional techniques and steps in filling an aerosol canister and attaching a metering valve to obtain a MDI suitable for the administration of pharmaceutical aerosol formulations and would have had a reasonable expectation of successfully following conventional techniques and steps. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6-7, 12-14, and 18-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-10, 21, and 32 of U.S. Patent No. 7,347,199 (USPN '199) in view of McNamara et al. (U.S. Patent No. 6,423,298).

It is noted that both sets of claims claim formulations or pressurized metered dose inhalers (pMDIs) containing formulations comprising dissolved salmeterol, a hydrofluorocarbon propellant (e.g. HFA 227, HFA 134a, or mixtures thereof), cosolvent (e.g. ethanol or polyethylene glycol). The primary difference between the claims of the instant application and the claims of USPN '199 is that the claims of USPN '199 do not recite the limitation that the compositions contain water in an amount of 0-5% w/w or added acid. The deficiency regarding the amount of water is prima facie obvious, because the claims of USPN '199 do not indicate that water has been added. Thus, the claims of USPN '199 necessarily comprise 0% w/w water and are an obvious variant of the claims of the instant application. It is noted that claim 10 of USPN '199 claims a pMDI wherein the active agent is a beta-adrenergic agonist selected from the group consisting of salbutamol, formoterol, salmeterol, and TA 2005, wherein the pMDI also contains in solution (i) propellant selected from HFA 227, HFA 134a, or mixtures thereof, (ii) ethanol as the co-solvent, and (iii) a low volatility component including glycerol, polyethylene glycol, etc. McNamara's teachings, set forth above cure the deficiency regarding the presence of

added acid. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-3, 6-7, 12-14, and 18-21 *prima facie* obvious over claims 7-10 of U.S. Patent No. 7,347,199 (USPN '199) McNamara et al. (U.S. Patent No. 6,423,298).

(1) Claims 1-3, 5-7, 9, 12, and 14-17 are provisionally rejected as being unpatentable over claims 2-3, 6-7, 11, 19, 22, 24, 28-32, 35-36, 40-47, 50-52 of copending Application No. 10/504,151 (copending '151) in view of Lewis et al. (U.S. Patent No. 6,716,414) ("Lewis"); and (2) claims 1-3, and 5 are provisionally rejected as being unpatentable over claims 14-15 and 25-26 of copending Application No. 11/408,026 (copending '026) in view of McNamara et al. (U.S. Patent No. 6,423,298).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are overlapping in scope and mutually obvious. Independent claim 1 of the instant application claims a pharmaceutical aerosol solution formulation comprising salmeterol active agent, HFA propellant, cosolvent, 0-5% w/w water (0% water reads on less than 500-1,500 ppm water), wherein the amount of cosolvent is no more than 35% w/w of the total weight of the formulation. Independent claim 32 of copending '151 claims a standard aluminum container containing a pharmaceutical aerosol solution formulation comprising (1) an active agent selected from formoterol or a stereoisomer, physiologically acceptable salt, and solvate thereof, (2) a liquefied HFA propellant, (3) a co-solvent (i.e. ethanol), (4) less than 1,500 ppm of water based on the total weight of the formulation, and (5) between 1.0% w/w and 20% w/w HCl present in an amount equivalent to between 0.030% and 0.045% w/w of 1M HCl. The cited dependent claims of the instant application and of copending

'151 have similar and overlapping co-solvent Markush groups, claimed particle sizes, pH ranges, additional active agent Markush groups, and the same steps in the claimed methods of preparing pharmaceutical formulations. The other cited dependent claims in both applications also recite the same or substantially similar limitations.

The primary difference between applications is that the claims of copending '151 require that the principal active agent is formoterol and excluding claim 14 of copending '151, the claims of the instant application do not specify the container material, and the claims of the cited copending Applications do not require added mineral acid. This deficiency is cured in part by the teachings of Lewis, which is solely provided to demonstrate that salmeterol, formoterol, and TA 2005 are art recognized as being beta2-agonist bronchodilators (col. 5, lines 30-33 of Lewis), and those are all expected to exhibit similar bronchodilating effects. McNamara's teachings, set forth above cure the deficiency regarding the presence of added acid in copending '026. Regarding the use of a standard aluminum canister, this would have been prima facie obvious modification, as evidenced by claim 13 of the instant application, which explicitly identifies standard aluminum as a suitable canister material. Therefore, it would have been obvious to substitute one beta2 agonist for another, to use standard aluminum as the canister material, and an ordinary skilled artisan would have had a reasonable expectation that upon substitution the resulting formulation would have similar bronchodilating properties. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-3, 5-7, 9-12, and 14-17 *prima facie* obvious over claims 2-3, 6-7, 11, 19, 22, 24, 28-32, 35-36, 40-47, 50-52of copending Application No. 10/504,151 (copending '867) in view of Lewis et al. (U.S. Patent No. 6,716,414) ("Lewis"). Similar reasoning was used in the analysis of copending

11/408,026 in view of McNamara et al. (U.S. Patent No. 6,423,298).

This is a provisional obviousness-type double patenting rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ashurst (WO 96/32151) is relevant, because it teaches suitable inert coatings for metered dose inhalers.

Claims 1-9 and 12-17 are rejected. Claims 18-22 are withdrawn by original presentation. Claim 17 is objected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, ~10:00-6:00 and Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/James H Alstrum-Acevedo/
Patent Examiner, Art Unit 1616
Technology Center 1600